WISCONSIN WELL WOMAN PROGRAM (WWWP)

CLINICAL GUIDELINES FOR BREAST AND CERVICAL CANCER SCREENING AND FOLLOW-UP

Management of Abnormal Clinical Breast Examination and Mammographic Findings

WWWP recommends that providers utilize the guidelines contained in ***Evaluation of Common Breast Problems: Guidance for Primary Care Providers*** by Blake Steele et al in CA – A Cancer Journal for Clinicians 48 (1): 49-63:1998 including the Appendix 1 ***Management of Common Breast Problems*** prepared by Society of Surgical Oncology and the Commission on Cancer of the American College of Surgeons and the Society of Surgical Oncology. Also, the WWWP recommends utilizing the algorithms from ***CDC Follow-up of Abnormal CBE and Mammographic Findings (1999).*** These are appended to this document.

Management of Abnormal Cervical Cytology

WWWP recommends the following minimum standard guidelines for management or follow-up of abnormal cervical cytology as identified with a Pap Smear. These guidelines provide a path to assure that any WWWP enrolled client who has an abnormal or suspicious screening result receives timely additional rescreening or diagnostic testing resulting in a diagnosis, and initiates treatment if treatment was recommended. The WWWP Cervical Care **algorithm** is appended.

Providers must use Clinical Laboratory Improvement Act (CLIA)-approved laboratories to read the Pap smear. The laboratories used to read the Pap must report cytology findings using the Bethesda System for consistency and as mandated by CDC. Providers need to utilize appropriate collection technique and educate clients about their actions that can affect the Pap result. Patient reliability, clinical presentation, and abnormal cervical cytology must be considered.

Providers may also reference an article Interim Guidelines for Management of Abnormal Cervical Cytology, JAMA, June 15, 1994. Vol. 271. No.23, 1886-1869.

Management Guidelines listed by THE BETHESDA SYSTEM Key Terminology

1. Adequacy of specimen

a. Unsatisfactory for evaluation:

1. Selected causes include:
   - Inappropriate labeling or lack of identifying information accompanies the specimen
   - Relevant clinical information is not provided
   - Inadequate number of well preserved and well-visualized squamous epithelial cells (covering less than 10% of the slide surface)
   - Partially obscuring blood, inflammation, thick areas, poor fixation, air drying artifact or contaminants affecting 75% or more of the epithelial cells
   - Unsatisfactory due to obscuring inflammation
   - Unsatisfactory Pap smear secondary to atrophic changes

2. In general, in laboratories employing TBS, rates of unsatisfactory specimens range from 0.5 to 2.0 percent. Rates significantly higher than this may imply either overuse of the unsatisfactory designation or poor Pap smear technique on the part of the provider.

3. Pap tests reported as unsatisfactory must be repeated.

b. Satisfactory for evaluation

c. Satisfactory for evaluation but limited by

1. Specimens in this category have been completely screened and contain no recognizable abnormal cells; however, a significant portion of the smear is obscured. Specimens may be designated as limited if any of the following apply:
   - Lack of pertinent clinical patient information (age, date of last menstrual period)
   - Partially obscuring blood, inflammation, thick areas, poor fixation, air drying artifact and other contaminant, which precludes interpretation of approximately 50-75% of the epithelial cells.
   - Lack of an endocervical /transformation zone component. Data regarding the utility of the endocervical component as a measure of predicting smear adequacy are conflicting. While most studies suggest that the detection of abnormalities is increased in those smears that have an endocervical component, others have failed to demonstrate this. The presence of an endocervical component does correlate with a higher detection of endocervical glandular abnormalities.

2. Appropriate management will depend upon the clinical situation. Routine rescreening may be appropriate if the patient is reliable for follow-up, has a history of previous normal smears, and has no definable risk factors. However, short term screening (repeat pap smear) in two to three months may be appropriate for the patient who may be unreliable for follow-up, has a history of previous abnormal cervical cytology, or has other defined risk factors.

2. General Categorization

a. Within normal limits

1. Annual screen

2. After a woman has had three, consecutive, normal Pap tests within a 5 year (60 month) period documented in the record, the Pap test may be performed every 3 years.

b. **Benign cellular changes including infection and reactive changes:**

1. Benign cellular changes include cytological changes related to the presence of various infectious organisms or nonspecific inflammation, as well as reactive changes that are benign in nature.

2. This is considered a benign category and does not connote a premalignant condition. Rescreen at routine interval.

3.Treat the cause of inflammation.

3. Descriptive Diagnosis Epithelial Abnormalities

a. Squamous Cell

1. Squamous Cell Carcinoma.

2. ASCUS, Atypical Squamous Cells of Undetermined Significance:

a. This category indicates Pap smears in which the cytologic changes exceed those attributable to benign or reactive processes but do not meet definitive criteria for the diagnosis of a squamous intraepithelial lesion. The diagnosis will frequently be qualified as favoring a reactive process or a squamous intraepithelial lesion.

b. It should be a diagnosis used sparingly by the laboratory. In general, this category should not account for more than 5-8% of the total volume of smears and should not exceed two to three times the laboratory's normal squamous intraepithelial lesion rate.

c. A number of management options exist for an ASCUS diagnosis depending upon the clinical circumstances and whether the diagnosis is further qualified as follows:

- Short term screening (repeating the pap smear every four to six months) for three times until three negative smears occur is an acceptable option when a reactive process is favored, the patient is reliable, and there is documentation of a lack of risk factors.

- If ASCUS is associated with significant inflammation and/or the presence of an identifiable infectious organism, treat the infectious process and repeat the pap smear in two to three months or colposcopy if high risk (such as pathologic qualifiers favor dysplasia, history of high risk type HPV_DNA, or unreliable patient).

- If the patient is postmenopausal and the ASCUS diagnosis is accompanied by significant atrophy and/or inflammation ("atrophic vaginitis") consider hormone treatment. If estrogen is contraindicated (Hx breast cancer, Hx endometrial cancer, Hx deep vein thrombosis) perform or refer the woman for colposcopy exam. If estrogen is not contraindicated, treat with topical estrogen x 3-4 weeks and repeat Pap smear within 1-2 weeks after completion of treatment or approximately two months after the original Pap smear. Colposcopy if abnormal or resume routine screen if not abnormal.
- If a statement indicating that a neoplastic process or LGSIL is favored qualifies the ASCUS diagnosis; the patient should be managed as if she had LGSIL.

- Colposcopy is essential if the diagnosis of ASCUS occurs in a client who had a previous ASCUS/ premalignant condition/ SIL, poor client reliability to return, altered immune status, or other high risk factor.

3. HGSIL, High Grade Squamous Intraepithelial Lesions:

a. CIN-2 (moderate dysplasia) and CIN-3 (severe dysplasia) Carcinoma in Situ

b. Additional diagnostics to include colposcopy and directed biopsy with endocervical curettage.

4. LSIL, Low Grade Squamous Intraepithelial Lesions:

a. Changes associated with human papilloma virus (HPV) infection (Koilocytotic Atypia) and CIN I (mild dysplasia)

b. It is important to remember that the patient with a cytological diagnosis of LSIL is at significant risk (approximately 5-15%) of harboring a synchronous high-grade lesion.

c. A number of management options exist for LSIL depending upon the clinical circumstances as follows:

- Short term screening (repeating the pap smear every four to six months) for three times until three negative smears occur is an acceptable option when a reactive process is favored, the patient is reliable, and there is documentation of a lack of risk factors. The decision to choose repeat smears for this diagnostic category over colposcopy should be made only after considerable discussion with the patient with regard to treatment options and the importance of follow-up. After three consecutive negative smears the patient can be returned to the routine screening protocol.

- Colposcopy, endocervical curettage, and directed biopsy of any abnormal area on the Ectocervix is also an appropriate option for any patient with a diagnosis of LSIL.

- Colposcopy, endocervical curettage, and directed biopsy of any abnormal area on the Ectocervix is essential if the a client had had previous ASCUS/premalignant change or SIL, altered immune status, poor patient reliability to return, or has other risk factors.

b. Glandular cell

1. Endometrial cells, cytologically benign, in post menopausal women

2. AGUS Atypical Glandular Cells of Undetermined Significance:

a. The category of AGUS includes a spectrum of abnormalities ranging from benign reactive atypias to endocervical or endometrial adenocarcinoma.

b. It is a diagnostic category, which should be used sparingly by the laboratory. Follow-up studies in most labs have demonstrated that this is a highly significant diagnosis, which includes a large number of high-grade squamous lesions as well as glandular lesions. This is also a category in which communication with the laboratory is important.

c. Laboratories are encouraged to qualify the diagnosis further as favoring an endocervical adenocarcinoma, a high-grade squamous lesion, or a benign reactive process to guide management for this diagnostic category.

d. If a serious lesion is strongly considered by the laboratory, then the endocervical canal needs evaluation and at a minimum requires a good endocervical curettage if not cone biopsy.

e. If an endometrial origin for the atypical glandular cells is suspected, endometrial curettage may also be required to resolve the abnormality.

3. Adenocarcinoma

Endocervical/endometrial/extrauterine origin or nonspecific

5. Other Malignant Neoplasms

6. Hormonal Evaluation